

B7 opening, a rim positioned adjacent to the fluid collection and retrieval opening, and threads positioned adjacent to the rim.

IN THE DRAWINGS:

Proposed drawing corrections to Fig. 11 are indicated in red ink.

REMARKS

Claims 1, 6-8, 11, and 13 stand rejected for anticipation under 35 U.S.C. § 102(e) United States Patent No. 6,318,776 to Lee (hereinafter "the Lee patent"). Claims 1, 6, 9-11, and 16-18 stand rejected for anticipation under 35 U.S.C. § 102(b) over United States Patent No. 1,457,657 to Fahsbender (hereinafter "the Fahsbender patent"). Claims 6, 11, 12, and 14 stand rejected for anticipation over United States Patent No. 2,450,193 to Galliano (hereinafter "the Galliano patent").

Claims 2-5 stand rejected for obviousness under 35 U.S.C. § 103(a) over United States Patent No. 5,202,094 to Jones in view of the Fahsbender or Galliano patents. Claim 15 stands rejected for obviousness under 35 U.S.C. § 103(a) in view of the Fahsbender patent, the Galliano patent, or the Lee patent.

As an initial starting point, the Lee patent is not a valid 35 U.S.C. §102(e) reference. The Lee patent was filed August 22, 2000. The present application claims the benefit of United States Provisional Patent Application Serial No. 60/216,592, filed July 7, 2000 (the enabling disclosure attached hereto). Therefore, claims 1, 6-8, 11, and 13 cannot be anticipated by the Lee patent.

After reviewing the prior art located by the Examiner, the Applicant has amended the specification and independent claims 1 and 2 to recite, in part, a bodily fluid collection system comprising a plastic specimen container used to collect bodily fluids.

The specimen container (12) in Figs. 10 and 11 of the originally filed and the subsequent formal drawings is shown with alternating broad and thin cross-sectional lines.

This well-recognized cross-hatching indicates that the specimen container body is made from synthetic resin or plastic. MPEP 608.02. Therefore, the addition of “plastic” in amended claim 1 is not new matter. The addition of the “to collect bodily fluids” is also not new matter. Page 1, lines 11-13 of the originally filed specification states that “doctors and other medical service providers routinely ask patients (or pets) for bodily fluids, such as urine samples. Urine samples are typically collected in a specimen container.” To make this point clearer, the specification and amended independent claims 1 and 2 explicitly recite the amended claim language.

Turning now to the claim rejections, none of the prior art references cited by the Examiner teach or reasonably suggest removably attaching a interior/exterior grip-type handle to a plastic specimen container. With respect to amended independent claim 1, the Fahsbender patent teaches a handle for gripping a container that is suitable for carrying caustic or thermally excited materials (column 1, lines 20-26). The Fahsbender patent does not teach or suggest a plastic specimen container. Therefore, independent claim 1 is not anticipated by either the Fahsbender patent. Dependent claims 16-18, which depend directly or indirectly from amended independent claim 1, are also not anticipated by the Fahsbender patent.

With further regard to the anticipation rejection of independent claim 1 in view of the Fahsbender patent, the Examiner indicates that the Fahsbender patent receptacle is fully capable of collecting urine. The Fahsbender patent is silent as to the type of material the receptacle is made from, but a reasonable reading of the patent indicates that it is most probably metal. First, the receptacle can be “highly heated”, which suggests metal. Second, as shown in Fig. 1, a compression force applied by jaw (10) pinches the receptacle at the bead (11) and at the lowermost portion of the jaw. The remaining portion of the jaw (10) is not in

direct contact with the inner wall of the receptacle. However, the structure (5) is in direct contact with the outer wall of the receptacle.

With continuing reference to Fig. 1 of the Fahsbender patent, when the jaw (10) is pulled against the inner wall of the receptacle, a force is applied to the inner wall of the receptacle by the jaw (10) only at the two ends of the jaw (10). However, the structure (5) is exerting a force to the exterior portion of the receptacle along an entire length of the jaw (10). The absence of force along the interior surface of the receptacle between the bead (11) end of the jaw (10) and the lowermost portion of the jaw (10), along with the presence of force along the outer surface of the receptacle opposite to the non-supported inner wall, will deform or crack the receptacle unless the receptacle material itself provides a force that is equal to the force being exerted on the exterior portion of the receptacle by the structure (5). Again, the physics favors metal over other types of materials.

With the preceding discussion in mind, the Applicant also submits Internet Dialogue on Ecological Sanitation, “Source Separation of Human Urine – Separation Efficiency and Effects of Water Emissions, Crop Yield, Energy Usage and Reliability”, Hakan Jonsson, Associate Professor, SLU, Swedish University of Agricultural Sciences, Sweden (15 November – 20 December 2001). The Jonsson article further addresses the point raised by the Examiner, namely that the container disclosed in the Fahsbender patent is fully capable of collecting urine. The Jonsson article states on page 3, seven lines from the bottom of the page, that it is advisable to “[a]void contact between urine and metals in the toilet and in the whole system. Urine is very corrosive and at excretion its concentration of heavy metals is very low. Metals in contact with urine will corrode and thus contaminate the urine.”

To tie the Applicant’s argument together, the Fahsbender patent does not disclose a receptacle having a specific material type, but certainly does not teach plastic.

Furthermore, the receptacle material type is most probable metal due to the direct teachings of the Fahsbender patent (heat and compression). However, as stated in the Jonsson article, a metal receptacle is not suitable for collecting a bodily fluid such as urine because urine is corrosive to metal. Therefore, the Fahsbender patent does not anticipate amended independent claim 1 of the present application.

In addition to the limitation of plastic, independent claim 1 recites that the handle is used during collection of a bodily fluid. The Fahsbender patent teaches carrying or lifting, but not collection. The Applicant's originally filed disclosure provides in-depth discussion about the problems associated with filling a specimen container.

Dependent claims 16-18, which depend directly or indirectly from independent claim 1, are also not anticipated by the Fahsbender patent. Dependent claim 16 has been amended to correct the antecedent basis error and to make dependent claim 16 consistent with amended independent claim 1. No new matter has been added.

Independent claim 6 has been substantially amended to include the general limitations recited in cancelled dependent claims 11 and 13, particularly that the first and second body members do not move with respect to one another when the locking member or pin is inserted through the first body member and the second body member. Independent claim 6 defines over the Fahsbender patent and the Galliano patent because the Fahsbender patent and the Galliano patent do not teach or suggest a locking member. Moreover, cancelled dependent claim 13 was originally rejected under the Lee patent, which is not prior art. Therefore, amended independent claim 6 and dependent claims 9, 10, 12, and 14 are not anticipated by the Fahsbender patent or the Galliano patent.

Dependent claim 9 has been amended to recite the "at least one notch" shown as numeral (56) in Fig. 10 and described on page 6, line 28, of the originally filed specification. Therefore, drawing corrections to Fig. 10 are not required. However, the

Applicant has also noted an error in Fig. 11, wherein the thread (58) is improperly labeled as notch (56). Applicant is attaching the proposed correction, indicated in red ink. Approval of the drawing correction is respectfully requested.

With respect to the obviousness rejections of claims 2-5 and 15, the Applicant makes these initial observations. First, the Applicant has amended independent claim 2 to generally include the limitations contained in amended independent claim 1, and particularly include the limitations that the specimen container is plastic and the plastic specimen container is used to collect bodily fluids. The relevance of these limitations is discussed above in connection with amended independent claim 1. Second, none of the art cited in this case shows the combination of a plastic specimen container and a handle that contacts an interior surface and an exterior surface of the plastic specimen container. Moreover, none of the prior art in this case teaches or suggests the claimed combination. To the contrary, the only patent that even discusses specimen containers is the Jones patent, and the handle in the Jones patent certainly does not contact an inner wall or surface of the specimen container.

It is hornbook patent law that claims cannot be rejected based upon hindsight, or the connection of one or more references to a particular claim without a corresponding teaching or connection between the references themselves. To wit, the Applicant also attaches a relatively recent Court of Appeal for the Federal Circuit decision with facts generally analogous to the facts in the present application.

In In re Dembiczak, 50 USPQ2d 1614 (Fed. Cir. 1999), the Court of Appeals for the Federal Circuit (CAFC) reversed a finding of obviousness from the Board of Patent Appeals and Interferences. An exemplary claim generally recited an orange plastic garbage bag having pumpkin-like facial indicia printed on an outer surface of the plastic garbage bag. The cited references included a standard orange colored plastic garbage bag and a book describing a method of making a paper bag pumpkin by stuffing the paper bag with

newspapers, painting the paper bag orange, and then adding facial features to the painted, stuffed bag.

The Board determined that the book taught all of the claim elements of the primary claim, with the exception of the orange plastic. To fill in this void, the Board found that substitution of the known orange plastic bag for the orange-colored paper bag was an obvious design choice.

In reversing the decision of the Board, the CAFC held that even though the combined references arguably fulfilled all of the claim elements, there was no reasonable teaching or suggestion in the cited references themselves to make the proposed combination.

The facts in the pending application are analogous to the facts presented in Dembiczak. The primary reference in Dembiczak taught all of the claim limitations except an orange plastic garbage bag. In the present case, the Examiner has indicated that the primary reference (Jones) teaches all of the claim limitations except for a handle that simultaneously grips an interior surface and an exterior surface of a claimed bodily fluid collection container.

In an attempt to perfect a *prima facie* finding of obviousness in Dembiczak, the Board substituted the conventional plastic garbage bag for the paper bag. However, the references themselves did not teach or suggest this proposed combination. In the pending application, the Examiner is attempting to combine the teachings of the Jones patent with the handles described in the Fahsbender patent or the Galliano patent. It is the position of the Applicant that the Jones patent, the Fahsbender patent, and the Galliano patent do not provide the requisite teaching or suggestion to make the proposed combination. The Jones patent certainly doesn't and the Jones patent is the only cited patent which shows a specimen cup. Only the Applicant's disclosure teaches or reasonably suggests the claimed combination.

Therefore, the proposed combination of the Jones patent, the Fahsbender patent, or the Galliano patent is invalid.

The proposed combination is also improper because one skilled in the art of bodily fluid container handles would not be enticed to look at the Fahsbender patent or the Galliano patent when attempting to solve a bodily fluid collection problem. The relevant specimen collection art, represented by the Jones patent, is replete with examples of specimen container handles that only grasp an outer surface of a specimen container. Therefore, one skilled in the art would focus on the teachings of these types of holders, since these patents represent the wisdom in the field at the time of the invention.

In summation, while it may be tempting to mosaic the Jones patent (or any other patent disclosing a plastic specimen collection container) with the Fahsbender patent or the Galliano patent (or any other patent teaching a grip-type handle) to arrive at the claimed invention, the proposed combination is not taught or suggested by the Jones patent, the Fahsbender patent, the Galliano patent, or any of the other references on the record. Therefore, amended independent claim 2 is patentable over the attempted combination of the cited references. Dependent claims 3-5 are also in condition for allowance by definition.

Dependent claim 15 depends directly from independent claim 6, which is in condition for allowance.


In final summation, the basic argument of the Applicant is that none of the art cited by the Examiner or submitted by the Applicant shows a grip-type handle removably attached to a plastic specimen container. Moreover, none of the cited prior art made of record in this case teaches removably grasping a plastic specimen container with a handle that contacts an interior surface of the plastic specimen container and an exterior surface of the plastic specimen container. Therefore, remaining claims 1-10, 12, and 14-18 are patentable

over the cited prior art. Reconsideration of the pending claim rejections and allowance of remaining claims 1-10, 12, and 14-18 are respectfully requested.

In order to speed up the prosecution of this case, the Examiner is encouraged to contact the undersigned at 412-471-8815 with any questions that this Amendment may raise.

Respectfully submitted,

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Marked-Up Versions of Claims 1-4, 6, 9, 12, and 16

1. (Twice Amended) A [urine] bodily fluid collection [device] system comprising:

a plastic specimen container to collect bodily fluids, the plastic specimen container comprising a plastic body [having] that defines an inner wall and an outer wall; and

a handle having a first body member and a second body member, the first body member having a first contact member which, in turn, has a first contact surface and an inner surface, and the second body member having a second contact member which, in turn, has a second contact surface and an outer surface,

wherein the first contact surface of the first contact member engages the inner wall of the [specimen container] plastic body, and the second contact surface of the second contact member engages the outer wall of the [specimen container] plastic body, removably securing the handle to the [specimen container] plastic body.

2. (Twice Amended) A method [of collecting urine] to collect a bodily fluid with a handle and a plastic specimen container [body], wherein the handle [has] comprises a first body member and a second body member, the first body member has a first contact member which has a first contact surface and an inner surface, the second body member has a second contact member which has a second contact surface and an outer surface, and the specimen container comprises a plastic body that defines [has] an inner wall and an outer wall, [defines] a collection cavity, and [forms] a rim, comprising the steps of:

a) positioning the first contact member of the first body member adjacent to the rim formed by the plastic specimen container body, with the first contact member protruding into the collection cavity and the first contact surface facing the inner wall of the plastic [specimen container] body;

b) positioning the second contact member of the second body member adjacent to the rim formed by the plastic [specimen container] body, with the second contact surface of the second contact member facing the outer wall of the plastic [specimen container] body; and

c) securing the handle to the rim of the plastic [specimen container] body so that the first contact surface of the first contact member engages the inner wall of the plastic [specimen container] body, and the second contact surface of the second contact member engages the outer wall of the plastic [specimen container] body.

3. (Once Amended) The method as claimed in claim 1 further comprising the step of moving the second contact member in a first direction prior to the step of securing the handle to the plastic [specimen container] body so that the first contact surface of the first contact member engages the inner wall of the plastic [specimen container] body, and the second contact surface of the second contact member engages the outer wall of the plastic [specimen container] body.

4. (Once Amended) The method as claimed in claim 2 further comprising the step of removing the handle from the plastic [specimen container] body after the step of securing the handle to the plastic [specimen container] body so that the first contact surface of the first contact member engages the inner wall of the plastic [specimen container] body, and the second contact surface of the second contact member engages the outer wall of the plastic [specimen container] body.

6. (Once Amended) A handle for use with a plastic specimen container [body, the specimen container body having an inner wall and an outer wall], the handle comprising:

a first body member [having a first contact member which, in turn, has a first contact surface and an inner surface; and] that defines a first contact surface and a guide hole;

a second body member [having a second contact member which, in turn, has a second contact surface and an outer surface,] that defines a second contact surface and a locking hole; and

a locking member,

wherein [the first contact surface engages the inner wall of the specimen container body and the second contact surface engages the outer wall of the specimen container, removably securing the handle to the specimen container body] the first body member and the second body member are movable with respect to one another until the guide hole and locking hold are aligned with one another and the locking member is inserted into the guide hole and the locking hole.

9. (Once Amended) The handle as claimed in claim 6, wherein the second contact surface defines [a plurality of notches] at least one notch.

12. (Once Amended) The handle as claimed in claim [11]6, wherein the first body member defines an internal channel, and the second body member is received in the internal channel defined by the first body member.

16. (Once Amended) The urine collection device as claimed in claim 1, wherein the [specimen container] plastic body defines a collection cavity, a fluid

collection and retrieval opening, a rim positioned adjacent to the fluid collection and retrieval opening, and threads positioned adjacent to the rim.

Marked-Up Version of change to the specification on page 2 immediately following the summary of the invention:

It is therefore an object of the present invention to provide a removable handle that securely holds many, if not all, standard plastic specimen containers used to collect bodily fluids.

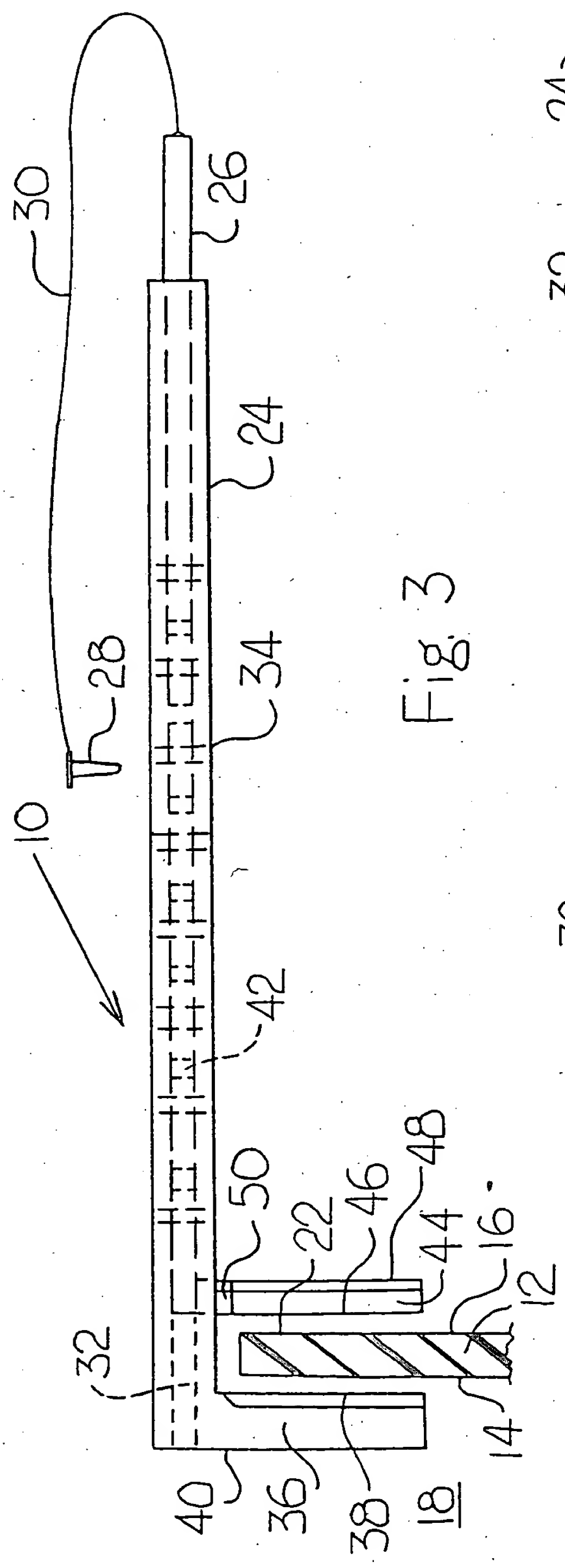


Fig. 3

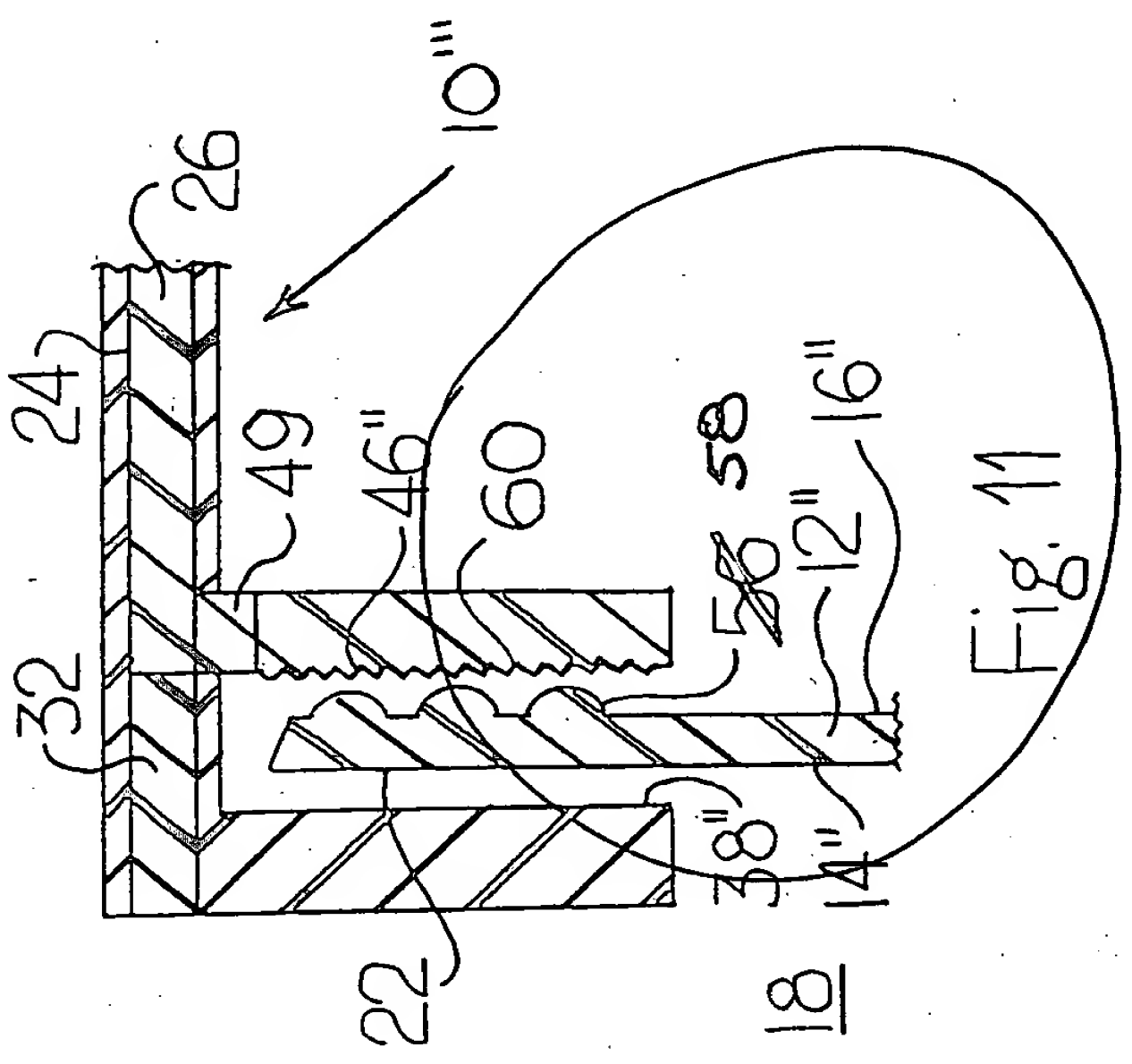


Fig. 11

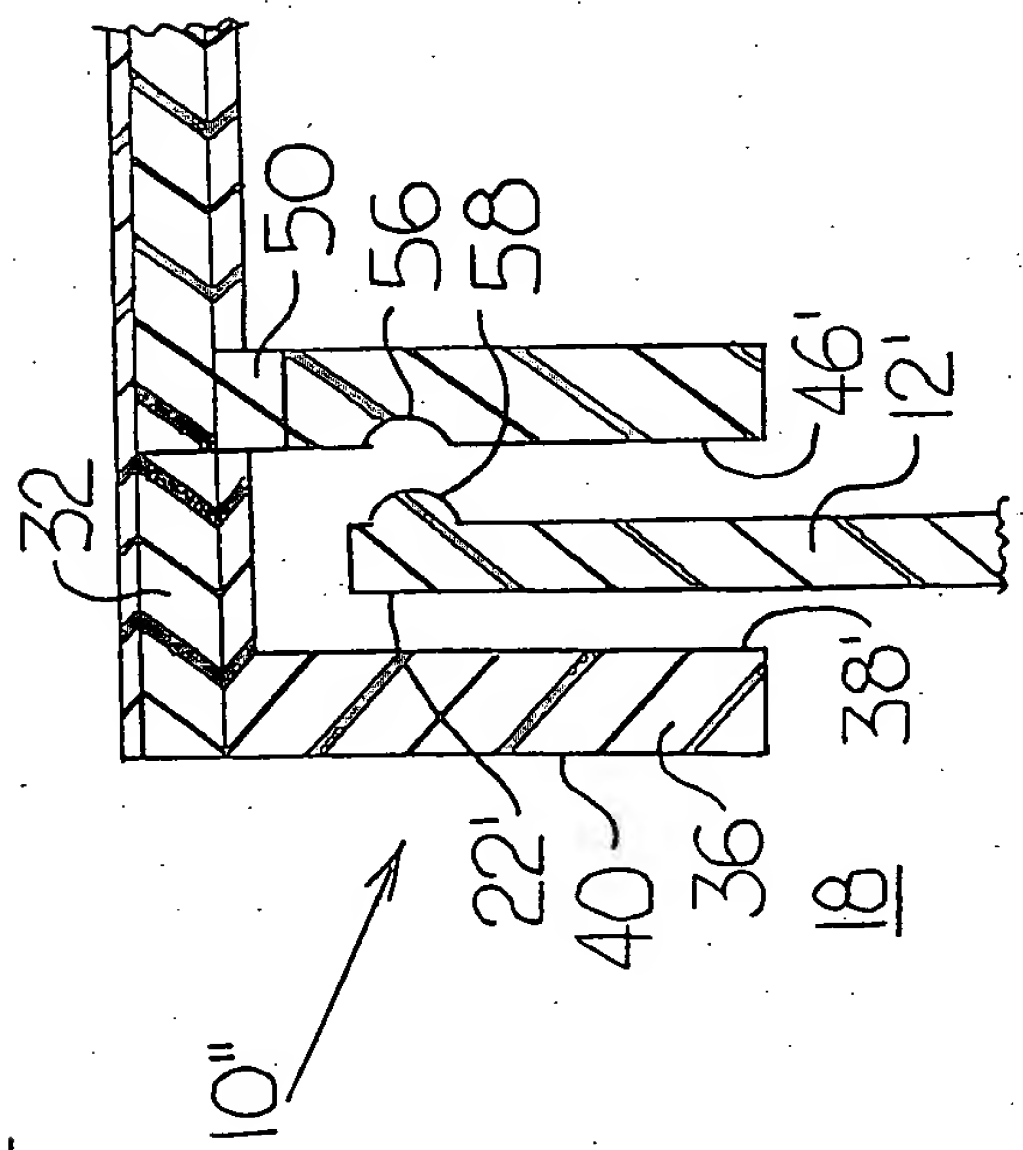


Fig. 10